

REMARKS

Entry of the foregoing, reexamination and further and favorable reconsideration of the subject application in light of the following remarks, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested.

As indicated in the Office Action Summary, claims 1-54 are pending in the instant application. Claims 28-54 stand withdrawn as directed to non-elected subject matter. Applicants gratefully acknowledge that claims 15-27 stand allowed.

By way of the present Amendment, claims 10-13 and 27 are amended. Basis for these amendments may be found in the specification and claims as filed, especially on page 3, lines 19-24 (which define tobacco leaves as tobacco which may not have completed the air-curing process, and which may be attached to the stalk of the tobacco plant) and lines 25-28 (which describe that curing comprises the drying process for newly harvested tobacco). Thus, no new matter is introduced by way of this Amendment.

Objections to the claims

Claim 27 stands objected to as purportedly depending from a claim which is not among the numbered claims. Claim 27 has been amended herein to depend from independent base claim 26. Thus, Applicants submit that this objection is obviated. Withdrawal of the objection to claim 27 is respectfully requested.

Claim Rejections - 35 U.S.C. § 112, second paragraph

Claims 10-14 stand rejected under 35 U.S.C. § 112, second paragraph, as purportedly indefinite. Applicants note with appreciation the indication in the present Office Action that these claims would be allowable if the rejections under 35 U.S.C. § 112, second paragraph are overcome.

Claims 10-11 stand rejected for the recitation of the phrase "said drying step" and "the darkened tobacco portion", as these phrases purportedly lack antecedent basis. Claims 10-11 have been amended to recite "air-curing" rather than "drying step", which has antecedent basis in base claim 7. Claim 10 has been amended to recite "a darkened tobacco portion" instead of "the darkened tobacco portion". Thus, Applicants submit that this rejection is obviated.

Claim 12 stands rejected for the recitation of the phrase "the primed leaves", as this phrase purportedly lacks antecedent basis. Claim 12 has been amended to recite "primed leaves" rather than "the primed leaves". Thus, Applicants submit that this rejection is obviated.

Claims 12-13 stand rejected, as it is purported unclear whether the phrases "air-cured tobacco plant" and "air-curing tobacco leaves" refer to the same thing. For clarification, claims 12-13 have been amended to recite "air-curing tobacco leaves" instead of "air-cured tobacco plant". Thus, Applicants submit that this rejection is obviated.

Claim Rejections - 35 U.S.C. § 103

Claims 1-9 stand rejected under 35 U.S.C. § 103(a) as purportedly unpatentable over Tso *et al.* (U.S. Patent No. 3,845,774). This rejection is respectfully traversed.

Claim 1 is directed to a tobacco leaf in a condition of having been contacted with a wash solution comprising an aqueous solution of a carbonate or bicarbonate salt and in a further condition of having been subsequently air cured. Claim 7 is directed to a process of air-curing tobacco leaves, the improvement comprising reducing air-curing time by treating the tobacco leaves with an alkaline curing accelerating agent. Applicants submit that the combinations set forth in independent claims 1 and 7 are not suggested by Tso *et al.*

In the Office Action, Tso *et al.* is cited for purportedly disclosing a method of curing tobacco, wherein a tobacco product that was subjected to curing is contacted with an aqueous alkali/basic solution. It is alleged in the Office Action that it would have been obvious to the skilled artisan to utilize salts known in the art to raise the pH levels of the tobacco of Tso *et al.*

Applicants respectfully traverse this rejection, on the grounds that the *prima facie* case of obviousness has not been established relative to the claimed invention, and on the grounds that the tobacco leaf recited in claim 1 and process recited in claim 7 provide unexpected results.

As set forth in M.P.E.P § 2142, in order to establish a *prima facie* case of obviousness, three criteria must be met, *i.e.*, (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings,

(2) there must be a reasonable expectation of success, and (3) the prior art references must teach or suggest all the claim limitations.

In the present case, 1) there is insufficient motivation to modify Tso *et al.* in the manner proposed in the Official Action, 2) there is no reasonable expectation of success of achieving the claimed method when modifying Tso *et al.*, 3) Tso *et al.* teach away from the claimed invention and 4) Tso *et al.* do not teach or suggest all of the claim limitations.

1) There is insufficient motivation to modify Tso et al.

The Office Action alleges that it would have been obvious to the skilled artisan to raise pH levels of the tobacco of Tso *et al.* by using salts well known in the art. Applicants submit that the skilled artisan, upon reading Tso *et al.*, would not have been led to wash tobacco leaves with a carbonate or bicarbonate solution, as required by claim 1. Tso *et al.* also fail to suggest the curing process recited in claim 7.

Specifically, Tso *et al.* disclose that chemicals and enzymes may be added to a tobacco homogenate to adjust the pH. Tso *et al.* disclose the homogenization of shredded tobacco leaves. Tso *et al.* further disclose that chemicals may be added, but that they must be added during the homogenizing process in which the shredded leaves are ground or blended (see column 2, lines 19-22). Thus, Tso *et al.* fail to suggest the combination of features recited in claim 1, which include a tobacco leaf contacted with a wash solution comprising an aqueous solution of a carbonate or bicarbonate salt and in a further condition of having been subsequently air cured. Tso *et al.* further fail to suggest the combination of features recited in claim 7, which include a process of air-curing tobacco leaves,

comprising reducing air-curing time by treating the tobacco leaves with an alkaline curing accelerating agent.

Moreover, Tso *et al.* do not teach or suggest that adjusting the pH or that adding any liquid for any reason would result in a reduction of tobacco-specific nitrosamines and bacterial endotoxins in the tobacco. Thus, it is submitted that the skilled artisan would not have been motivated to modify Tso *et al.* in a manner which would result in the claimed invention.

2) There is no reasonable expectation of success of achieving the claimed invention when modifying Tso et al.

The Office Action asserts that it would have been obvious to the skilled artisan to raise pH levels of the tobacco of Tso *et al.* by using salts well known in the art to treat the tobacco. However, it is further submitted that the skilled artisan would not have had a reasonable expectation of success of achieving the claimed invention when modifying Tso *et al.*, because Tso *et al.* do not teach or even suggest to the skilled artisan that adding any liquid would result in a reduction of tobacco-specific nitrosamines and endotoxins in the tobacco.

3) Tso et al. teach away from the claimed invention

Tso *et al.* teach away from the claimed invention in that Tso *et al.* require tobacco leaves to be ground into a homogenized mass to allow manipulation of leaf characteristics (*see* column 1, lines 32-54). In contrast, the present invention as claimed in claims 1 and 7

is directed to tobacco leaves. Thus, Tso *et al.* lead the skilled artisan away from the claimed invention, and the skilled artisan would not have had any expectation of success of achieving the claimed invention.

4. Tso et al. fail to teach or suggest each element of the claimed invention

Applicants further submit that Tso *et al.* fail to render the claimed invention obvious, because Tso *et al.* fail to teach or suggest each and every element of the claimed invention. The combination of features recited in claim 1 is directed to a tobacco leaf which has been contacted with a wash solution comprising an aqueous solution of carbonate or bicarbonate salt, and then which is subsequently cured. The combination of features recited in claim 7 is directed to a process of air-curing tobacco leaves by treating the leaves with an alkaline curing agent.

Tso *et al.* disclose homogenization of harvested tobacco leaves. Specifically, tobacco leaves are cut in 5/64 of an inch or smaller, and then homogenized in a blender or grinder. The homogenized material is incubated and then cured. Tso *et al.* disclose that chemicals may be added during homogenization.

Thus, Tso *et al.* fail to disclose or suggest a tobacco leaf contacted with a wash solution of carbonate or bicarbonate, as recited in claim 1. Claim 7 is directed to the treatment of tobacco leaves with an alkaline wash. In contrast, Tso *et al.* disclose the homogenization of shredded tobacco leaves. Tso *et al.* disclose that chemicals may be added, but that they must be added during the homogenizing process in which the shredded leaves are ground or blended (see column 2, lines 19-22).

Accordingly, the claimed invention is patentable over Tso *et al.*

Surprising and Unexpected Results

It is a well established legal precedent that the presence of an unexpected, advantageous or superior result is evidence of nonobviousness. *See* M.P.E.P. § 716.02(a); *In re Papesch*, 315 F.2d 381, 137 U.S.P.Q. 43 (C.C.P.A. 1963). Along these lines, it is also well established that "a greater than expected result" is evidence of nonobviousness. *See* M.P.E.P. § 716.02(a); *In re Corkill*, 711 F.2d 1496, 226 U.S.P.Q. 1005 (Fed. Cir. 1985).

Applicants submit that the tobacco leaf recited in claim 1 and the process recited in claim 7 provide surprising and unexpected results in reducing tobacco-specific nitrosamines and bacterial endotoxins. Applicants have discovered that tobacco-specific nitrosamines and endotoxins can be reduced in tobacco leaves by washing the leaves with an alkaline solution before curing. Applicants surprisingly discovered that the treatment of tobacco leaves with an aqueous solution of carbonate or bicarbonate anions prior to curing will accelerate the coloring of the tobacco during curing. Further, Applicants unexpectedly discovered that when this treatment is coupled with immediate drying of the tobacco at the conclusion of the curing process, there are pronounced reductions in tobacco-specific nitrosamines and bacterial endotoxins in tobacco. *See* the present specification, page 13, line 28 to page 14, line 12. Thus, any *prima facie* case of obviousness based on Tso *et al.* is rebutted by such unexpected results.

Therefore, it is submitted that Tso *et al.* fail to render the claimed invention obvious because there is insufficient motivation to modify Tso *et al.*, there is no reasonable

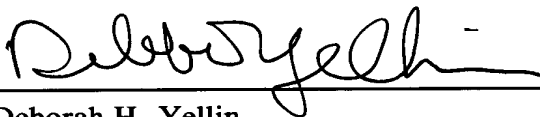
expectation of success of achieving the claimed method when modifying Tso *et al.*, the cited reference teaches away from the claimed method and Tso *et al.* fail to teach or suggest each and every element recited in claims 1 and 7. Further, Applicants' claimed invention achieves surprising and unexpected results. Thus, Applicants respectfully request withdrawal of this rejection.

CONCLUSION

Applicants respectfully submit that the application is in condition for allowance. Favorable consideration on the merits and prompt allowance are respectfully requested. In the event any questions arise regarding this communication or the application in general, the Examiner is invited to contact Applicants' undersigned representative at the telephone number listed below.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By: 
Deborah H. Yellin
Registration No. 45,904

P.O. Box 1404
Alexandria, Virginia 22313-1404
(703) 836-6620

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Attachment to Amendment and Reply

Marked-Up Claims 10-13 and 27

10. (Once Amended) The process of Claim 8, wherein the air-curing [said drying step] includes the step of reducing moisture content of a [the] darkened tobacco portion to a preselected, final moisture content in the range of 10 to 30%.

11. (Once Amended) The process of Claim 10, wherein the air-curing time is [said drying step being] initiated and completed within 7 days.

12. (Once Amended) The process according to Claim 10, further comprising the steps of selectively stripping brown leaves from [an] air-cured tobacco leaves [plant] during the air-curing, the method further comprising drying [the] primed leaves apart from remaining leaves on the plant.

13. (Once Amended) The process according to Claim 10, wherein brown leaves are primed from [an] air-cured tobacco leaves [plant] during the air-curing, the method further comprising drying the primed leaves after removing midveins of the primed leaves.

27. (Once Amended) The method of Claim 26 [64], wherein said curing-accelerating agent comprises a carbonate and/or bicarbonate salt.